

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/568,695

Applicant(s)

TANAKA ET AL.

Examiner

STEPHEN KAPUSHOC

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 December 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): The rejection of claim 4 because claim 4 is now cancelled.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: none.
Claim(s) objected to: none.
Claim(s) rejected: 1.
Claim(s) withdrawn from consideration: 5-13.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634

Continuation of 11, does NOT place the application in condition for allowance because:

Applicants arguments in traversal of the rejection of claims under 35 USC 112 1st paragraph for lack of enablement have been fully and carefully considered but are not found to be persuasive to withdraw the rejection. Applicants have argued that several citations (p.7-8 of Remarks) of post-filing art support the association required by the claimed method (i.e. C at 3279 of SEQ ID NO: 1 indicates increased risk of myocardial infarction (MI)). However, the Examiner maintains that the cited references of Yamada et al and Asselbergs et al have limited relevance to the claimed methods which require MI, whereas the Yamada et al and Asselbergs et al do not particularly discuss MI. Similarly, it is not clear that Ohnishi et al discloses any association related to the same SNP as required by the claims. The cited Ozaki et al reference appears to contain data regarding a sample population that is partly examined by the disclosure of the instant specification, and as such does not help to provide additional evidence of a reliable association where the reference instead merely supplies an analysis of the same subjects as the instant specification. Finally, Szolnoki et al does not appear to provide any data in support of the required association, but merely asserts in the Abstract that some prior references assert a potential mechanism of SNP:risk association, where such an assertion is not evidence of a reliable association between genotype and MI risk.

Applicants have further argued (p.9 of Remarks) that the claimed method does not require undue experimentation. The Examiner maintains that the claimed method is not merely a method of genotyping, but a method that requires knowledge of a robust and reliable association between genotype and risk of MI. As such, given the unpredictability established by the art with regard to the required ghenotype:phenotype association, the skilled artisan would be required to perform an analysis to in fact establish that such a relationship exists.

Finally it is noted that Applicants arguments regarding the art cited by the Examiner (i.e.: Mangino et al; Sedlacek et al; and Kimura et al) has been addressed in the previous Office Action of 07/23/2009.